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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/044,486 | 01/11/2002 | Roger Y. Tsien | | 9885 |

7590 08/02/2006
THE REGENTS OF THE UNIVERSITY OF CALIFORNIA
1111 FRANKLIN STREET, FIFTH FLOOR
OAKLAND, CA 94607

EXAMINER

BERCH, MARK L

ART UNIT PAPER NUMBER

1624

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|--|--------------------------------------|-------------------------------------|--|
| <p align="center">Advisory Action Before the Filing of an Appeal Brief</p> | Application No. 10/044,486 | Applicant(s) TSIEN ET AL. | |
| | Examiner Mark L. Berch | Art Unit 1624 | |

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 April 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 20 April 2006. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
 (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
 (b) ☒ They raise the issue of new matter (see NOTE below);
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See memo. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
 5. ☐ Applicant's reply has overcome the following rejection(s): _____.
 6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
 The status of the claim(s) is (or will be) as follows:
 Claim(s) allowed: 1, 2, 17 and 18.
 Claim(s) objected to: _____.
 Claim(s) rejected: 19 and 20.
 Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See memo.
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____.
 13. ☐ Other: _____.

Mark L. Berch
Primary Examiner
Art Unit: 1624

DETAILED ACTION

The amendment filed 4/20/06 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because: The proposed amendment raises new issues that would require further consideration and/or search.

The amendment to claim 1 clearly introduces new matter new matter. No such formula exists in the specification. This would permit any Z group to be linked via the new double bond linkage. There is no such teaching in the specification. Applicants point to figures 1-6 and paragraph 0050. However, these all show just one Z choice, not the generic concept of any Z being double bonded to the rest of the molecule. The remarks say that the examiner's argument "overlooks the teachings of the specification" --- but where is such a teaching? Similarly, applicants say that the examiner "fails to broadly construe the terms as required" --- but what term is it that the examiner has failed to "broadly construe". Thus, the species still fail to fall within the ambit of Formula I, as set forth in the specification. Applicants have not explained how Formula I can be construed to embrace these compounds of claims 19-20. As stated previously, compounds for Formula I have a CH₂ groups attached to the cephalosporin, and Z is attached via a single bond. These species meet neither requirement. Instead, these have an extra -CH=CH- inserted in between the C-3 carbon on the cephalosporin and the C to which the Z group is attached. That is, they have the form Cephalosporin-(extra -CH=CH-)-CH₂-Z. The extra vinylene is seen only for one choice of Z; it is not taught for Z generally.

Further, the amendment to claim 17 makes no sense at all. The new formula in claim 17 requires a double bonded Z group, but none of those actually listed in claim 17 have provision for a double bond. Note that R3 is in all cases a single bond.


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With regard to the "enzymatic fragmentation" issue, as the examiner has noted, that does provide utility for the particular species where A is S, i.e. $n=0$. But claim 19 has other choice, i.e. $n=1$ or 2, and indeed, claim 20 excludes the $n=0$ species. Applicants point to figures 4-6, but it is not at all clear how these constitute utility. Figure 4, the only one to mention the $n=2$ compounds, does not deal at all with utility, but rather with stability.

Applicants point out that working examples are not required to support a claim, but the examiner has not pointed to a lack of working examples, but rather to the fact that the compound does not fall within Formula I.

It may well be that the case should have been filed with the vinylene group present (i.e. that Formula I as written is defective), but it was in fact filed with the group absent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Mark L. Berch
Primary Examiner
Art Unit 1624

4/26/2006